K060132

MAR 16 2006

510 (k) Summary of Safety and Effectiveness

Date Summary Prepared: January 16, 2006

Submitter Information: Spinal USA
213 Eastside Lane
Brandon, MS 39047

Contact Name: Jeffrey Johnson
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Device Trade Name: Spinal USA Cement Restrictor System

Common Name: Prosthesis, Hip, Cement Restrictor

Regulatory Number: 878.3300

Classification: Class II

Product Code: JDK

INTENDED USE:
The Spinal USA Cement Restrictor System is intended as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

DEVICE DESCRIPTION:
The Spinal USA Cement Restrictor is a hollow rounded rectangular frame with various holes located throughout its geometry to hold bone cement. The exterior surface of the device has teeth on two opposing flat sides to prevent migration. The device comes in various sizes and is offered in straight and tapered styles. The device may be made from titanium alloy as specified in ASTM F136 or polyetheretherketone (PEEK) that conforms to ASTM F2026-02.

EQUIVALENT DEVICE:
The Spinal USA Cement Restrictor System was demonstrated to be substantially equivalent to previous cleared devices such as the Scient'X Cement Restrictor (K052367), Quantum Cement Restrictor (K040276), and Fortitude Cement Restrictor (K021719). The subject device and predicate devices have the following similarities:
-the same indication for use
-the same operating principle
-the same basic design
-the same materials
-implanted using the same surgical techniques and equipment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

Spinal USA
C/o Mr. Jeffrey Johnson
Manager, Regulatory Affairs
213 Eastside Lane
Brandon, Mississippi 39047

Re: K060132
Trade/Device Name: Spinal USA Cement Restrictor System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: January 16, 2006
Received: January 19, 2006

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.
The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 060132

Indications for Use

510(k) Number (if known): _____

Device Name: Spinal USA Cement Restrictor System

Indications for Use:

The Spinal USA Cement Restrictor System is intended as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060132